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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
SHERR-UNA BOOKER, an individual, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**PLAINTIFF SHERR-UNA'S CONTROVERTING STATEMENT OF FACTS TO DEFENDANTS' SEPARATE STATEMENT OF FACTS IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT AS TO PLAINTIFF SHERR-UNA BOOKER**

In response to each of the paragraphs in Defendants' Separate Statement of Facts ("Bard SOF") [Doc. 7352], Plaintiff Sherr-Una Booker responds as follows:

1. Plaintiff Sherr-una Booker received a Bard G2® Filter (the "Filter") on June 21, 2007, before she underwent [redacted]. (Ex. A, Plaintiff Fact Sheet of Plaintiff Sherr-Una Booker (hereinafter "PFS"), §§ II.1, II.2(a).)

Plaintiff's Response: **Admit.**

2. The Filter is not sold directly to patients. (Ex. B, G2 Filter Instructions for Use (the "G2 IFU"), at page 1.)

Plaintiff's Response: Dispute. Defendants' exhibit does not properly support their assertion of fact as required by Rule 56(c). The G2 IFU cited by Defendants

states, "Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician." As such, the G2 IFU does not support Defendants' contention that the filter is not sold directly to patients.

3. Plaintiff's implanting physician, [redacted]. (Ex. C, March 21, 2017 Dr. Marcus D'Ayala Deposition Transcript ("D'Ayala Dep. Tr.") at 95:10 16 to 96:13.)

Plaintiff's Response: Admit.

4. [redacted] had the IFU that accompanied the Filter available to him to read. (Ex. C, D'Ayala Dep. Tr. at 94:20 to 95:2.)

Plaintiff's Response: Admit.

5. The G2 IFU applicable in June 2007 (when Plaintiff received her Filter) included the following warnings:

a. Under the bolded heading "Potential Complications," the G2 IFU reads as follows:

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
- Perforation or other acute or chronic damage of the IVC wall.

* * *

- All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the

> use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

(Ex. B, G2 IFU.)

Plaintiff's Response: **Admit.**

6. Plaintiff's expert, Dr. Derek Muehrcke, acknowledges that all IVC filters are known to have potential complications, including filter fracture, migration, tilt, and perforation. (Ex. D, July 24, 2017 Dr. Derek Muehrcke Deposition Transcript ("Muehrcke Dep. Tr.") at 55:22 to 57:9.)

Plaintiff's Response: **Dispute. Dr. Muehrcke testified that some filters are much less likely to have the potential complication of tilt. Ex. A, Muehrcke Dep. Tr. at 56:12-16. Dr. Muehrcke also testified that the Bard G2 filter had an unacceptable caudal migration risk which Bard had been aware of since late 2005, early 2006, resulting in an unacceptable safety profile for the G2 filter. *Id.* at 58:2-24.**

7. Dr. Muehrcke testified that "[e]very filter can have a complication;" therefore, it would be "unrealistic" for a physician implanting a Bard IVC filter to expect that the filter would never migrate, tilt, perforate, or fracture. (Ex. D, Muehrcke Dep. Tr. at 102:16 to 103:2.)

Plaintiff's Response: **Dispute. The summary of testimony set forth in paragraph 7 is a mischaracterization of Dr. Muehrcke's testimony. Dr. Muehrcke testified, "The Bard filter has all these problems. The other filters have—like, the TrapEase and OptEase have a problem with cable thrombosis. You know, the—the—the Bard filter not only has a higher rate of individual complication, but it has a lot more of several complications." Ex. A, Muehrcke Dep. Tr. at 102:9-23. In response to being asked if he believed that a physician implanting a Bard filter has an expectation that under no circumstances, in no scenario, no matter what happens,**

that filter will not migrate, Dr. Muehrcke responded that would be an "unrealistic expectation. I think that the filters can have problems." *Id.*

8. [redacted] was well aware of the risks associated with IVC filters, including the risks of fracture, movement, migration, embolization, and perforation when he implanted the Filter. (Ex. C, [redacted] Dep. Tr. at 93:10 to 95:5.)

Plaintiff's Response: Dispute. [redacted] was not "well aware" of the risks associated with the G2 filter; [redacted] testified that he was aware of the potential complications of the G2 filter that were reported at the time of implant. Ex. B, [redacted] Dep. Tr. at 93:10-19. The Bard G2 IFU that was available at the time of Ms. Booker's implant states, "Most cases of filter fracture, however, have been reported without any adverse clinical sequelae." Fractures beyond the implantation procedure are only mentioned in the "Potential Complications" section of the IFU. Ex. C, Bard G2 IFU.

9. [redacted] was aware of the risk of fracture associated with the Filter and took this risk into consideration when weighing the risks and benefits of implanting the Filter in Ms. Booker. (Ex. C, [redacted] Dep. Tr. at 95:1-9.)

Plaintiff's Response: Dispute. [redacted] testified he was not fully aware of the risk of fracture associated with the Bard G2 filter. Therefore, [redacted] could not have taken all factors into consideration when weighing the risks and benefits of implanting the Bard G2 filter in Ms. Booker. [redacted] was never told by his Bard sales rep that there was a 530% higher fracture rate over other filters on the market for the Recovery or a 1200% higher risk of death from Recovery fracture and embolization to the heart. Ex. B, [redacted] Dep. Tr. at 34:7-35:2. He was not aware that in 2004, through an independent investigator, Bard evaluated the high number of adverse events of the Recovery filter, nor was [redacted] informed of the results of that investigation. *Id.* at 33:17-34:5. [redacted] was not aware of Bard's Crisis Management Plan, in effect as early as 2004, to address the high rates of adverse events, such as perforation, fracture and migration.

_Id._ at 33:10-15. [redacted] testified he would have liked to have known this information in 2004-2005 before he implanted Ms. Booker with the G2 filter. _Id._ at 36:11-37:13. [redacted] also testified that the adverse events analysis reports and the MAUDE information would have been important information to know and would have influenced his prescribing habits. _Id._ at 37:15-10; 43:20-44:1. The information contained in the 2004 health hazard evaluation, prepared by David Ciavarella, MD, Vice President of Clinical Affairs at Bard, showing higher fracture rates in the Recovery filter when compared to other filters would have been important information for [redacted] to have. _Id._ 36:11-37:20. In addition, Dr. [redacted] would have liked to have known about the Recovery filter migration Remedial Action Plan dated January 4, 2005. _Id._ at 37:22-40:2. [redacted] may have used a filter other than a Bard filter. _Id._ at 37:15-10; 63:19-64:2. Further, Dr. [redacted] stopped using Bard filters, specifically the G2 filter, because the complication rates were not as "low and acceptable" as he initially anticipated. _Id._ at 110:23-15; 114:16-25.

10. [redacted] does not recall specific discussions with any Bard sales representatives regarding the Filter. (Ex. C, [redacted] Dep. Tr. at 114:8-15.)

Plaintiff's Response: Dispute in part. Plaintiff agrees that [redacted] testified that he did not recall specific conversations with Bard sales representatives; however, as is set out in response to 9 above he testified that he was never told certain information by anyone at Bard, including the sales representatives.

11. Although [redacted] testified on occasion that he would have "wanted to know" certain alleged factual information presented by Plaintiff's counsel, he admitted that it would be "[d]ifficult to say with certainty" whether the information he was shown would have changed his prescribing decision, and that it "would depend upon what other filters we had at the time and what their problems would have been." (Ex. C, [redacted] Dep. Tr. at 63:22-25.)

Plaintiff's Response: **Dispute. The testimony Bard cites is incomplete. [redacted] testified, "With regards to the Bard filter, would I have used a different device if I knew at the time that the Bard filter was not ideal or as good as some of the other implants? The answer would have to be yes...I would have used a different filter if there was a different filter that I knew of that was better, in terms of its safety profile." Ex. B, [redacted] Dep. Tr. at 61:24-63:9. When [redacted] was asked if he would have used a different filter if he knew all the information that the investigation revealed he responded, "Difficult to say with certainty. It would depend upon what other filters we had at the time and what their problems would have been. But it would have been a very important piece of information, as far as making decisions regarding this or any other patient, yes." *Id.* at 63:10-64:2.**

12. [redacted] testified that "you have to have a way of treating these difficult patients. So some filter has to be used. And it becomes a matter of deciding which filter is best, so to speak. And sometimes that's not entirely clear." (Ex. C, [redacted] Dep. Tr. at 70:21-25.)

Plaintiff's Response: **Dispute. This is an incomplete representation of [redacted] testimony. The testimony reads, Q: "If you knew back in 2007 when you were implanting that filter that there was even a 12 percent probability of fracture with the filter, would you have used a G2?" A: "Unlikely" Q: "if there was a 25 percent risk of filter fracture, can we safely say you would not have used that filter?" A: "Most likely." [redacted] continued to answer as quoted by Defendants. Ex. B, [redacted] Dep. Tr. at 70:9-25.**

13. [redacted] testified that the information that Plaintiff's counsel showed him was not peer-reviewed or reliable information, and that it is important to have complete and reliable information when deciding whether or not he would have prescribed the Filter. (Ex. C, [redacted] Dep. Tr. at 121:12 to 122:1.)

Plaintiff's Response: **Dispute in part. [redacted] did not testify that "the information that Plaintiff's counsel showed him was not peer-reviewed or**

reliable information" He did testify that it is important to have complete and reliable information when deciding to prescribe an IVC filter. Ex. B, [redacted] Dep. Tr at 121:21-122:1.

The deposition transcript accurately reads as follows:

> **QUESTION BY MS. KATE HELM: (Bard's attorney) What you have not been provided today is with any peer-reviewed or reliable information showing that those "ifs" are, in fact, true: is that right?"**
>
> **MR. DAVID MATTHEWS: (Plaintiff's attorney) Object to the form.**
>
> **MR. PHILLIP LERNER: (Dr. D'Ayala's personal attorney who was present at the deposition). That's more of a statement than a question, don't' you think?**
>
> **THE WITNESS: I agree.**

The witness, [redacted], is agreeing with the assessment of his attorney, Mr. Phillip Lerner. He did not agree to the content of the question here. *Id.* at 121:12-19.

Moreover, [redacted] testified that the Nicholson article, the Journal of Vascular and Interventional Radiology article, the Deso article that he was shown were all peer-reviewed. *Id.* at 122:11-125:25.

14. [redacted] does not rely on information contained in a medical device manufacturer's internal documents, or their preliminary or internal investigations, when deciding which IVC filter to use because such incomplete information is unreliable, misleading, and could negatively impact his practice. (Ex. C, [redacted] Dep. Tr. at 106:7 to 107:7.)

Plaintiff's Response: Dispute in part. Plaintiff does not dispute that this testimony was given by [redacted], but this testimony must be considered in the context of the preceding question and answer (Q. And what you rely on is the manufacturer of medical devices to provide you with reliable information about the device; is that fair? A. Yes) and Dr. [redacted] other testimony that he would have

liked to have known about the data that was available to Bard beginning in 2004. (*See* testimony set forth in 9, 10, 11, and 13 above).

15. [redacted] relies on reliable information from device manufacturers as well as his experience, the experience of his colleagues, the FDA, and the applicable medical literature when deciding which IVC filter to use. (Ex. C, [redacted] Dep. Tr. at 20 105:12 to 106:7.)

Plaintiff's Response: Dispute in part. [redacted] provided this testimony, however, he also testified that he would like to have had the additional information known by Bard as early as 2004 and set forth in 9, 10, 11, and 13 above. [redacted] testified that he also relies on the MAUDE database reports of problems and the literature regarding filter fragmentation and migration. These reports were among the reasons [redacted] stopped using Bard filters. Ex. B, [redacted] Dep. Tr. at 31:13-32:1.

16. [redacted] (Ex. B, [redacted] 24 Dep. Tr. at 96:17 to 98:6.)

Plaintiff's Response: Dispute. [redacted]. Ex. B, [redacted] Dep. Tr. at 28:19-29:20. Further, Dr. [redacted] testified that he does not recall Ms. Booker personally. *Id.* at 13:9-16.

The Bard G2 IFU that was available at the time of Ms. Booker's implant, (June 2007) is titled "G2 FILTER SYSTEM for Permanent Placement." It contains the following language:

- **"The G2 Filter is designed to act as a permanent filter."**

- **"The G2 Filter System-Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:"**
- **"The safety and effectiveness of the G2Filter System for use as a retrievable or temporary filter have not been established."**

Ex. C, Bard G2 IFU.

17. It was not [redacted] practice in 2007 to provide Plaintiff with any written materials about the Filter or the procedure or to give her a copy of the IFU. (Ex. C, [redacted] Dep. Tr. at 98:8-15.)

Plaintiff's Response: Admit.

18. [redacted] (Ex. E, February 20, 2017 Plaintiff Sherr-una Booker Deposition Transcript, ("Booker Dep. Tr.") at 90:25 to 91:5; 163:5-12.)

Plaintiff's Response: Dispute. [redacted] **. Ex. G, Booker Dep. Tr. at 181:1-8; 185:13-16.** [redacted] **. *Id.* at 181:1-8; 185:23 -186:4; 186:21-24. However, she is not a physician. *Id.* at 195:25-196:6.**

19. Ms. Booker does [redacted] (Ex. A, PFS at § 11.13(b); Ex. E, Booker Dep. Tr., at 218:24 to 223:13.)

Plaintiff's Response: Dispute in part. [redacted] **. Ex. G, Booker Dep. Tr. at 222: 5-19.** [redacted] ***Id.* at 202:14-21; 203:11-23; 208:10-209:4; 236:9-18.** [redacted]

[redacted] ***Id.* at 215:24-216:7.**

20. [redacted]. (Ex. F, Selected Plaintiff Medical Records, at BOOKERS_GWIMC_MDR01365-1366; BOOKERS_GWIMC_MDR01379-1381.)

Plaintiff's Response: **Admit.**

21. [redacted] (Ex. F, Selected Plaintiff Medical Records, at BOOKERS_ 20 GWIMC_MDR01355-1356.)

Plaintiff's Response: **Admit.**

22. [redacted]. (Ex. F, Selected Plaintiff Medical Records, at BOOKERS_GWIMC_MDR00724-726.)

Plaintiff's Response: **Admit.**

23. [redacted]. (Id.)

Plaintiff's Response: **Disputed in part.** [redacted] **. Ex. D, Kang Dep. Tr. at 145:9-22.**

24. [redacted]

[redacted]. (Ex. F, Selected Plaintiff Medical Records, at BOOKERS_GWIMC_MDR00724-726; BOOKERS_GWIMC_MDR00719.)

Plaintiff's Response: **Dispute** [redacted] **Ex. D, Kang Dep. Tr. at 104:9-12.** [redacted] ***Id.* at 38:5-24.** [redacted] ***Id.* at 39:3-24.** [redacted] ***Id.* at 40:15-24.** [redacted] ***Id.* "** [redacted] ***Id.* at 41:4-22.**

25. [redacted] (Ex. F, Selected Plaintiff Medical Records, at BOOKERS_GWIMC_MDR00810-811; Ex. G, March 22, 2017 Dr. Salil Patel Deposition Transcript ("Patel Dep. Tr.") at 104:14 to 105:4; Ex. H, June 20, 2017 Dr. Richard Harvey Deposition Transcript ("Harvey Dep. Tr.") at 91:1-11.)

Plaintiff's Response: **Dispute.** [redacted] **Ex. D, Kang Dep. Tr. at 46:23-47:18.**

26. [redacted]

[redacted] (Ex. F, Selected Plaintiff Medical Records, at BOOKERS_GWIMC_MDR00447-449.)

Plaintiff's Response: **Dispute.** [redacted]

27. [redacted] (Ex. F, Selected Plaintiff Medical Records, at BOOKERS_GWIMC_MDR00447-449.)

Plaintiff's Response: **Dispute.** [redacted] **Ex. E, Plaintiff Medical Records at BOOKERS_GWIMC _MDR00447-449.**

28. [redacted]. (Ex. E, Booker Dep. Tr. at 202:8 to 203:4.)

Plaintiff's Response: **Dispute in part.** [redacted] **Ex. G, Booker Dep. Tr. at 202:22-203:4. Dr. Hurst has testified that any sharp foreign body has a risk of causing a problem. Ex. F, Hurst Dep. Tr. at 179:11-16.** [redacted] **Ex. F, Hurst Dep. Tr. at 185:10-17.** [redacted]. **Ex. A, Muehrcke Dep. Tr. at 169:3-16.**

29. Plaintiff does not remember receiving any written information or brochure regarding her IVC filter. (Ex. E, Booker Dep. Tr. at 162:11-19.)

Plaintiff's Response: **Admit. Plaintiff admits that she cannot remember whether or not she received any written material or brochure regarding the filter**

because she was so concerned at the time with her cancer. Ex. G, Booker Dep. Tr. at 162:11-16.

30. Plaintiff has never spoken to anyone at Bard. (Ex. E, Booker Dep. Tr. at 251:20-24.)

Plaintiff's Response: **Admit.**

31. Plaintiff did not know that Bard was the manufacturer of her IVC filter until after she contacted her lawyer about her potential legal claim. (Ex. E, Booker Dep. Tr. at 166:10-12.)

Plaintiff's Response: **Admit.**

32. There is no evidence establishing that the Filter deviated from Bard manufacturing specifications for other G2 Filters in its lot or deviated from its design specifications.

Plaintiff's Response: **Admit.**

33. Plaintiff's engineering expert, Dr. McMeeking, stated that he does not know how Bard IVC Filters look coming off of the manufacturing line. (Ex. I, April 22, 2014 Robert McMeeking Deposition Transcript ("McMeeking Dep. Tr.") at 146:15 to 147:4; 268:25 to 269:3.)

Plaintiff's Response: **Admit.**

34. Plaintiff's materials science expert, Dr. Ritchie, testified that he is not familiar with the manufacturing process utilized by Bard to make the Filter "in a detailed sense," acknowledging that "I don't have a great recall of what exactly I read [regarding manufacturing specifications for Bard filters]." (Ex. J, May 8, 2014 Dr. Robert Ritchie Deposition Transcript ("Ritchie Dep. Tr.") at 65:13 to 66:6.)

Plaintiff's Response: **Admit.**

35. Moreover, Plaintiff's experts have examined the Filter and have failed to identify how, if at all, it varied from other G2 filters coming off the line or deviated from its design specifications. While Dr. Ritchie observed possible indications of a surface defect on the Filter that possibly initiated a fracture, he testified "I'm not absolutely

certain that it's there, but inclusions are not uncommon in these materials, and generally they initiate cracks. And without cutting that out precisely, you can't be certain." (Ex. K, August 4, 2017, Dr. Robert Ritchie Deposition Transcript ("Ritchie Dep. Tr. II") at 75:14 to 76:1; 81:17-22.)

Plaintiff's Response: **Admit.**

36. The Filter was cleared by the FDA for permanent use on August 29, 2005, and for retrievable use on January 15, 2008 through the 510(k) process outlined in the Food, Drug, and Cosmetic Act. (Ex. L, August 29, 2005 FDA Clearance Letter; Ex. M, January 15, 2008 FDA Clearance Letter.)

Plaintiff's Response: **Admit.**

RESPECTFULLY SUBMITTED this 12th day of October 2017.

GALLAGHER & KENNEDY, P.A.

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of October 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti